

CLAIMS

1. An isolated polypeptide comprising an immunogenic portion of a breast protein or a variant of said protein that differs only in conservative substitutions and/or modifications, wherein said protein comprises an amino acid sequence encoded by a polynucleotide molecule comprising a sequence selected from the group consisting of: (a) nucleotide sequences recited in SEQ ID NOS: 3, 10, 17, 24, 45-52, 55-67, 72, 73, and 89-94; (b) complements of said nucleotide sequences; and (c) sequences that hybridize to a sequence of (a) or (b) under moderately stringent conditions.
2. An isolated polynucleotide molecule comprising a nucleotide sequence encoding the polypeptide of claim 1.
3. An isolated polynucleotide molecule comprising a sequence provided in SEQ ID NOS: 3, 10, 17, 24, 45-52, 55-67, 72, 73, and 89-94.
4. An expression vector comprising a polynucleotide molecule according to any one of claims 2 and 3.
5. A host cell transformed with the expression vector of claim 4.
6. The host cell of claim 5 wherein the host cell is selected from the group consisting of *E. coli*, yeast and mammalian cell lines.
7. A pharmaceutical composition comprising the polypeptide of claim 1 and a physiologically acceptable carrier.
8. A vaccine comprising the polypeptide of claim 1 and a non-specific immune response enhancer.
9. The vaccine of claim 8 wherein the non-specific immune response enhancer is an adjuvant.

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10. A vaccine comprising a polynucleotide molecule of any one of claims 2 and 3 and a non-specific immune response enhancer.

11. The vaccine of claim 10 wherein the non-specific immune response enhancer is an adjuvant.

12. A pharmaceutical composition for the treatment of breast cancer comprising a polypeptide and a physiologically acceptable carrier, the polypeptide comprising an immunogenic portion of a breast protein, wherein said protein comprises an amino acid sequence encoded by a polynucleotide molecule comprising a sequence selected from the group consisting of: (a) nucleotide sequences recited in SEQ ID NOS: 1, 2, 4-9, 11-16, 18-23, 25-44, 53, 54, 68-71, and 74-88; (b) complements of said nucleotide sequences; and (c) sequences that hybridize to a sequence of (a) or (b) under moderately stringent conditions.

13. A vaccine for the treatment of breast cancer comprising a polypeptide and a non-specific immune response enhancer, said polypeptide comprising an immunogenic portion of a breast protein, wherein said protein comprises an amino acid sequence encoded by a polynucleotide molecule comprising a sequence selected from the group consisting of: (a) nucleotide sequences recited in SEQ ID NOS: 1, 2, 4-9, 11-16, 18-23, 25-44, 53, 54, 68-71, and 74-88; (b) complements of said nucleotide sequences; and (c) sequences that hybridize to a sequence of (a) or (b) under moderately stringent conditions.

14. The vaccine of claim 13 wherein the non-specific immune response enhancer is an adjuvant.

15. A vaccine for the treatment of breast cancer comprising a polynucleotide molecule and a non-specific immune response enhancer, the polynucleotide molecule comprising a sequence selected from the group consisting of: (a) nucleotide sequences recited in SEQ ID NOS: 1, 2, 4-9, 11-16, 18-23, 25-44, 53, 54, 68-71, and 74-88;

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(b) complements of said nucleotide sequences; and (c) sequences that hybridize to a sequence of (a) or (b) under moderately stringent conditions.

16. The vaccine of claim 15, wherein the non-specific immune response enhancer is an adjuvant.

17. A pharmaceutical composition according to claims 7 or 12, for use in the manufacture of a medicament for inhibiting the development of breast cancer in a patient.

18. A vaccine according to any one of claims 8, 10, 13 or 15, for use in the manufacture of a medicament for inhibiting the development of breast cancer in a patient.

19. A fusion protein comprising at least one polypeptide according to claim 1.

20. A pharmaceutical composition comprising a fusion protein according to claim 19 and a physiologically acceptable carrier.

21. A vaccine comprising a fusion protein according to claim 19 and a non-specific immune response enhancer.

22. The vaccine of claim 21 wherein the non-specific immune response enhancer is an adjuvant.

23. A pharmaceutical composition according to claim 20, for use in manufacture of a medicament for inhibiting the development of breast cancer in a patient.

24. A vaccine according to claim 21, for use in the manufacture of a medicament for inhibiting the development of breast cancer in a patient.

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25. A method for detecting breast cancer in a patient, comprising:
(a) contacting a biological sample from a patient with a binding agent which is capable of binding to a polypeptide, the polypeptide comprising an immunogenic portion of a breast protein, wherein said protein comprises an amino acid sequence encoded by a polynucleotide molecule comprising a sequence selected from the group consisting of nucleotide sequences recited in SEQ ID NOS: 1-94, complements of said nucleotide sequences and sequences that hybridize to a sequence provided in SEQ ID NO: 1-94 under moderately stringent conditions; and

(b) detecting in the sample a protein or polypeptide that binds to the binding agent, thereby detecting breast cancer in the patient.

26. The method of claim 25 wherein the binding agent is a monoclonal antibody.

27. The method of claim 26 wherein the binding agent is a polyclonal antibody.

28. A method for monitoring the progression of breast cancer in a patient, comprising:

(a) contacting a biological sample from a patient with a binding agent that is capable of binding to a polypeptide, said polypeptide comprising an immunogenic portion of a breast protein, wherein said protein comprises an amino acid sequence encoded by a polynucleotide molecule comprising a sequence selected from the group consisting of nucleotide sequences recited in SEQ ID NOS: 1-94, complements of said nucleotide sequences and sequences that hybridize to a sequence provided in SEQ ID NO: 1-94 under moderately stringent conditions;

(b) determining in the sample an amount of a protein or polypeptide that binds to the binding agent;

(c) repeating steps (a) and (b); and

(d) comparing the amount of polypeptide detected in steps (b) and (c) to monitor the progression of breast cancer in the patient.

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29. A monoclonal antibody that binds to a polypeptide comprising an immunogenic portion of a breast protein or a variant of said protein that differs only in conservative substitutions and/or modifications, wherein said protein comprises an amino acid sequence encoded by a polynucleotide molecule comprising a sequence selected from the group consisting of: (a) nucleotide sequences recited in SEQ ID NOS: 3, 10, 17, 24, 45-52, 55-67, 72, 73, and 89-94; (b) complements of said nucleotide sequences; and (c) sequences that hybridize to a sequence of (a) or (b) under moderately stringent conditions.

30. A monoclonal antibody according to claim 29, for use in the manufacture of a medicament for inhibiting the development of breast cancer in a patient.

31. The monoclonal antibody of claim 30 wherein the monoclonal antibody is conjugated to a therapeutic agent.

32. A method for detecting breast cancer in a patient comprising:

(a) contacting a biological sample from a patient with at least two oligonucleotide primers in a polymerase chain reaction, wherein at least one of the oligonucleotides is specific for a polynucleotide molecule encoding a polypeptide comprising an immunogenic portion of a breast protein, said protein comprising an amino acid sequence encoded by a polynucleotide molecule comprising a sequence selected from the group consisting of nucleotide sequences recited in SEQ ID NO: 1-94, complements of said nucleotide sequences and sequences that hybridize to a sequence of SEQ ID NO: 1-94 under moderately stringent conditions; and

(b) detecting in the sample a polynucleotide sequence that amplifies in the presence of the oligonucleotide primers, thereby detecting breast cancer.

33. The method of claim 32, wherein at least one of the oligonucleotide primers comprises at least about 10 contiguous nucleotides of a polynucleotide molecule comprising a sequence selected from SEQ ID NOS: 1-94.

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34. A diagnostic kit comprising:
- (a) one or more monoclonal antibodies of claim 29; and
 - (b) a detection reagent.
35. A diagnostic kit comprising:
- (a) one or more monoclonal antibodies that bind to a polypeptide encoded by a polynucleotide molecule comprising a nucleotide sequence selected from the group consisting of SEQ ID NOS: 1, 2, 4-9, 11-16, 18-23, 25-44, 53, 54, 68-71, and 74-88, complements of said sequences and sequences that hybridize to a sequence of SEQ ID NO: 1, 2, 4-9, 11-16, 18-23, 25-44, 53, 54, 68-71, or 74-88 under moderately stringent conditions; and
 - (b) a detection reagent.
36. The kit of claims 34 or 35 wherein the monoclonal antibodies are immobilized on a solid support.
37. The kit of claim 36 wherein the solid support comprises nitrocellulose, latex or a plastic material.
38. The kit of claims 34 or 35 wherein the detection reagent comprises a reporter group conjugated to a binding agent.
39. The kit of claim 38 wherein the binding agent is selected from the group consisting of anti-immunoglobulins, Protein G, Protein A and lectins.
40. The kit of claim 38 wherein the reporter group is selected from the group consisting of radioisotopes, fluorescent groups, luminescent groups, enzymes, biotin and dye particles.
41. A diagnostic kit comprising at least two oligonucleotide primers, at least one of the oligonucleotide primers being specific for a polynucleotide molecule encoding a polypeptide comprising an immunogenic portion of a breast protein, said protein

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comprising an amino acid sequence encoded by a polynucleotide molecule comprising a sequence selected from the group consisting of nucleotide sequences recited in SEQ ID NOS: 1-94, complements of said nucleotide sequences and sequences that hybridize to a sequence of SEQ ID NO: 1-94 under moderately stringent conditions.

42. A diagnostic kit of claim 41 wherein at least one of the oligonucleotide primers comprises at least about 10 contiguous nucleotides of a polynucleotide molecule comprising a sequence selected from SEQ ID NOS: 1-94.

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43. A method for detecting breast cancer in a patient, comprising:

- (a) obtaining a biological sample from the patient;
- (b) contacting the biological sample with an oligonucleotide probe specific for a polynucleotide molecule encoding a polypeptide comprising an immunogenic portion of a breast protein, said protein comprising an amino acid sequence encoded by a polynucleotide molecule comprising a sequence selected from the group consisting of nucleotide sequences recited in SEQ ID NOS: 1-94, complements of said nucleotide sequences and sequences that hybridize to a sequence of SEQ ID NO: 1-94 under moderately stringent conditions; and
- (c) detecting in the sample a polynucleotide sequence that hybridizes to the oligonucleotide probe, thereby detecting breast cancer in the patient.

44. The method of claim 43 wherein the oligonucleotide probe comprises at least about 15 contiguous nucleotides of a polynucleotide molecule comprising a sequence selected from the group consisting of SEQ ID NOS: 1-94.

45. A diagnostic kit comprising an oligonucleotide probe specific for a polynucleotide molecule encoding a polypeptide comprising an immunogenic portion of a breast protein, said protein comprising an amino acid sequence encoded by a polynucleotide molecule comprising a sequence selected from the group consisting of nucleotide sequences recited in SEQ ID NOS: 1-94, complements of said nucleotide sequences, and sequences that hybridize to a sequence of SEQ ID NO: 1-94 under moderately stringent conditions.

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47. Peripheral blood cells from a patient incubated in the presence of at least one polypeptide of claim 1, such that T cells proliferate, for use in the manufacture of a medicament for treating breast cancer in a patient.

49. A composition for the treatment of breast cancer in a patient, comprising T cells proliferated in the presence of a polypeptide of claim 1, in combination with a pharmaceutically acceptable carrier.

51. The cells of claim 50 wherein the antigen presenting cells are selected from the group consisting of dendritic and macrophage cells.

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